REMARKS

Claims 1-25, 27-31 and 33-36 are pending in the instant application. Claims 1-4 have been rejected. Claims 5-25 and 27-36 have been withdrawn from consideration. Claims 5-25 and 36 have been objected to. Claim 1-25, 27-31 and 33-36 have been canceled. Claim 37-62 have been added. No new matter has been added by this amendment. Reconsideration is respectfully requested in light of the following remarks.

I. Election/Restriction Requirement Under 35 U.S.C. §121

Applicants' arguments concerning the restriction requirement dated March 6, 2008 have not been found persuasive. It is suggested the U.S. Patent Nos. 4,474,813 and U.S. Patent No. 3,995,060 teach formulations containing unmilled flutamide. The restriction of the claims into Groups I (claims 1-26 and 36) and II (claims 27-35) has therefore been deemed proper and made final. However, the species election requirement has been withdrawn. While not specified in the Detailed Action, Applicants will assume, for the sake of facilitating the prosecution of this application, that the Examiner intended to withdraw claims 27-31 and 33-35 from further consideration as being drawn to non-elected subject matter. Accordingly, Applicants are canceling claims 27-31 and 33-35 without prejudice, reserving the right to file continuing applications for the canceled subject matter.

II. Information Disclosure Statement

Applicants acknowledge the Examiner's consideration of the references cited in the Information Disclosure statement filed September 21, 2006.

III. Priority

Applicants acknowledge grant of priority to German Patent Application Serial No. 10 2004 014 272.6, filed March 22, 2004.

IV. Specification

The Examiner notes the use of trademarks EULEXIN, TWEENs, COLLETTE VACTRON, LODIGE, DIOSNA and BOHLE-VAGUMAT. Applicants are requested to correct any errors identified in the specification. Accordingly, Applicants have amended the specification to appropriately refer to trademarks therein. For example, the second full paragraph at page 3 has been amended to refer to EULEXIN® (flutamide capsules) as supported by the teachings of U.S. Patent No. 6,228,401 (Test Procedure I; IDS Ref. AD). Moreover, the third full paragraph at page 10 has been amended to specify that the BOHLE-VAGUMAT® is a mixer, as supported by the preceding text of this paragraph.

V. Objections to the Claims

Claim 5-25 and 36 have been objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claims should refer to other claims in the alternative only. The Examiner indicates that claims 5-25 have not been further treated on their merits and claims 1-4 are under examination in the instant Office Action. In an earnest effort to advance the prosecution of this application, Applicants have canceled claims 1-25 and 36 and present new claims 37-62, which are fully supported by claims 1-25 and 36 as originally filed and amended in the preliminary amendments of September 21, 2006 and July 7, 2008. Because new claims 36-60 meet the requirements of 37 CFR

1.75(c), it is respectfully requested that this objection be reconsidered and withdrawn.

VI. Rejection of the Claims Under 35 U.S.C. §102/§103

Claims 1-4 have been rejected under 35 U.S.C. 102(b) as being anticipated by Neri et al. (U.S. Patent No. 4,474,813). It is suggested that this patent teaches a pharmaceutical composition comprising flutamide, which is necessarily either crystalline and/or amorphous, sodium lauryl sulfate (a surface active substance), magnesium stearate (a flow regulator) *inter alia*, which are mixed using a wet granulation method. It is suggested that wet granulation is not milling and therefore the flutamide is unmilled. It is suggested that the mixture is formed into tablets and a filling for capsules, as well as a suppository.

Claim 1 has been further rejected under 35 U.S.C. 102(b) as being anticipated by Neri et al. (U.S. Patent No. 3,995,060). It is suggested that this patent teaches pharmaceutical compositions comprising flutamide, which is necessarily either crystalline and/or amorphous, sodium lauryl sulfate (a surface active substance), which are mixed in a bowel. It is suggested that the mixture is not milled until subsequent steps, wherein step 3 (lines 21-23) admits that the first milling contains unmilled fractions of flutamide and sodium lauryl sulfate.

Claims 2-4 have also been rejected under 35 U.S.C. 103(a) as being unpatentable over Neri et al. (U.S. Patent No. 3,995,060). The Examiner acknowledges that Neri et al. do not specifically teach what form (milled or unmilled) the flutamide in these formulations is in. However, it is suggested that because the

capsule formulation of column 16 specifies that the flutamide is milled and Neri et al. suggest milled and unmilled flutamide for use in a pharmaceutical composition, one of ordinary skill in the art could infer that the tablet and capsule formulations of column 15 comprise unmilled flutamide since it is not specified that the flutamide is milled.

Applicants respectfully disagree with these rejections under 35 U.S.C. 102(b) and 103(a).

As clearly described in the first paragraph at page 8 and the first through fourth paragraphs at page 10 of the instant specification, a pharmaceutical formulation containing unmilled flutamide, which has been subjected to intensive mixing (*e.g.*, for 1 to 180 minutes) with a forced-action mixer in the presence of at least one surface-active substance, exhibits not only reproducible, but also higher rates of release of flutamide than formulations including micronised flutamide. Indeed, as evident from the data presented in the Table at page 17, the highest rate of release of active ingredient was obtained with a formulation composed of unmilled flutamide that was intensively mixed with a surface-active substance with a forced-action mixer.

Accordingly, in an earnest effort to highlight the distinct character of the instant pharmaceutical formulation, new claims 37-62 specify that the pharmaceutical composition is prepared by intensive mixing with a forced-action mixer, which imparts a high rate of release to the instant composition. Support for the features of new claims 37-62 is found in claim 27-36 as originally filed and in paragraphs one to four at page 10.

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently

described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). See MPEP 2131.

Similarly, MPEP 2143 indicates that in order to support a *prima facie* case of obviousness, all the claimed elements must have been known in the prior art such that one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination yielded nothing more than predictable results to one of ordinary skill in the art. *KSR*, 550 U.S. at ___, 82 USPQ2d at 1395; *Sakraida v. AG Pro, Inc.*, 425 U.S. 273, 282, 189 USPQ 449, 453 (1976); *Anderson's-Black Rock, Inc. v. Pavement Salvage Co.*, 396 U.S. 57, 62-63, 163 USPQ 673, 675 (1969); *Great Atlantic & P. Tea Co. v. Supermarket Equipment Corp.*, 340 U.S. 147, 152, 87 USPQ 303, 306 (1950).

While the '813 patent and '060 patents to Neri et al. teach a pharmaceutical composition produced by mixing the ingredients in a bowel with subsequent milling (Steps 1-3 at column 17 of the '060 patent) or blending ingredients by wet granulation (column 2, lines 36-39, and column 3, lines 1-2 of the '813 patent), these references do not teach or suggest crystalline and/or amorphous unmilled flutamide particles mixed with at least one surface-active substance, wherein the flutamide has been subjected to intensive mixing in a forced-action mixture with the at least one surface-active substance as presently claimed. In this regard, the flutamide compositions of Neri et al. would not be expected to exhibit the rate of release of the instant flutamide composition. Compare, for example, the rate of release of the compositions of Examples 2, 5 and 6 to the rate of release

of the compositions of Examples 1, 3 and 4 (*i.e.*, unmilled flutamide, intensively mixed) described in the Table at page 17 of the instant specification.

Because the cited references fail to teach each and every element of the claims as currently presented, these references cannot be held to anticipate or make obvious the present invention. It is therefore respectfully requested that these rejections under 35 U.S.C. 102(b) and 103(a) be reconsidered and withdrawn.

VII. Conclusion

Applicants believe that the foregoing comprises a full and complete response to the Office Action of record. Accordingly, favorable reconsideration and subsequent allowance of the pending claims is earnestly solicited.

Respectfully submitted,

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